

# United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,960	07/25/2003	Ary S. Chernomorsky	RUBI5873	2271
22430	7590 12/30/2005		EXAMINER	
YOUNG LAW FIRM			DAWSON, GLENN K	
A PROFESSIONAL CORPORATION 4370 ALPINE ROAD SUITE 106			ART UNIT	PAPER NUMBER
PORTOLA VALLEY, CA 94028			3731	

DATE MAILED: 12/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

				Talk		
		Application No.	Applicant(s)			
		10/627,960	CHERNOMORSKY ET	۲AL.		
	Office Action Summary	Examiner	Art Unit			
		Glenn K. Dawson	3731			
Period fo	The MAILING DATE of this communication app or Reply	pears on the cover sheet with t	he correspondence addres	SS		
WHIC - Exter after - If NO - Failu Any I	ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DAISIONS of time may be available under the provisions of 37 CFR 1.1: SIX (6) MONTHS from the mailing date of this communication. It period for reply is specified above, the maximum statutory period or reply within the set or extended period for reply will, by statute reply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICAT 36(a). In no event, however, may a reply l vill apply and will expire SIX (6) MONTHS , cause the application to become ABAND	TION.  be timely filed  from the mailing date of this commu  ONED (35 U.S.C. § 133).			
Status						
1)⊠	Responsive to communication(s) filed on 14 O	<u>ctober 2005</u> .				
2a)⊠	This action is <b>FINAL</b> . 2b) This	action is non-final.				
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
	closed in accordance with the practice under E	Ex parte Quayle, 1935 C.D. 11	I, 453 O.G. 213.			
Dispositi	on of Claims			· /		
5)⊠ 6)⊠ 7)⊠	Claim(s) <u>1-7,10,12-19,21-69 and 71-136</u> is/are 4a) Of the above claim(s) <u>71-73</u> is/are withdraw Claim(s) <u>1-7,10,12-19,21-39 and 74-136</u> is/are Claim(s) <u>40-57,61,62 and 64-69</u> is/are rejected Claim(s) <u>58-60 and 63</u> is/are objected to. Claim(s) are subject to restriction and/o	vn from consideration. e allowed. d.				
Applicati	on Papers					
10)	The specification is objected to by the Examine The drawing(s) filed on is/are: a) acc Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct The oath or declaration is objected to by the Ex	epted or b) objected to by t drawing(s) be held in abeyance. tion is required if the drawing(s) is	See 37 CFR 1.85(a). s objected to. See 37 CFR 1			
Priority ι	under 35 U.S.C. § 119		,			
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
2) Notice 3) Information	et(s)  te of References Cited (PTO-892)  te of Draftsperson's Patent Drawing Review (PTO-948)  mation Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  tr No(s)/Mail Date 07-01-2005.		mary (PTO-413) ail Date nal Patent Application (PTO-15)	2)		

#### Election/Restrictions

Claims 71-73 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 04-22-2005.

# Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 40-42,50,51,53-57 and 64-66 are rejected under 35 U.S.C. 102(b) as being anticipated by Krajicek-5522840.

Krajicek discloses a swellable collagen plug made out of two facing layers. The two layers have different degrees of cross-linking by the tanning process which causes the two portions to swell differently upon receipt of body fluids. See col. 3 lines 7-38. See Chvapil-4193813 col. 9 lines 3-14 for evidence of differential tanning producing differential cross-linking densities.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 67 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krajicek-'840 in view of Li-6090996.

Krajicek discloses the invention as claimed with the exception of the type of cross-linking. Li discloses that it was known to cross-link collagen matrixes by formaldehyde, glutaraldehyde or a dehydrothermal process. See col. 1 lines 24-30; col. 2 lines 21-31; col. 3 lines 29-64; col. 4 lines 21-29 and 48-60; and col. 5 lines 19-24. It would not have involved an inventive step to have used the cross-linking methods of Li in making the implant of Krajicek, as these methods have been shown to be effective at forming a stable matrix.

Claim 69 is rejected under 35 U.S.C. 103(a) as being unpatentable over Krajicek-'840 in view of Rhee, et al. 5510418.

Krajicek discloses the invention as claimed with the exception of cross-linking the matrix by a combination of both cyanamide and a dehydrothermal process. As both of

Art Unit: 3731

these methods were known, as taught by Rhee in col. 2 lines 38-45, to have used both of the cross-linking methods of Rhee in making the implant of Krajicek would not have involved an inventive step as these methods have been shown to be individually effective at forming a stable matrix, and using both would have produced a stable matrix as well.

Page 4

Claims 43,46-49 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krajicek-'840 in view of Fulton, et al.-6270464.

Krajicek discloses the implant as claimed with the exception of the additives in the matrix. Fulton discloses the use of the claimed additives. See col. 2 lines 28-55 and col. 3 lines 50-60. It would not have involved an inventive step to have added the contrast agents and the bioactive agents, as these would allow for non-invasive detecting of the position of implantation of the plug and would allow for the clotting of blood and the prevention of infection.

Claims 43,44,45,48,49,52,61 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krajicek-'840 in view of Sing, et al.-6183497.

Krajicek discloses the invention as claimed with the exception of the additives.

Sing discloses the use of radiopaque materials, radioactive materials and thrombin.

See col. 2 lines 52-59; col. 3 lines 11-20 and 45-60; and col. 8 lines 24-38. It would not have involved an inventive step to have added the additives of Sing to the plug of Krajicek, as these materials allow for blood clotting, treatment of cancerous cells and non-invasive imaging of the location of the plug in the patient's body.

## Response to Arguments

Applicant's arguments filed 10-14-2005 have been fully considered but they are not persuasive.

The examiner indicated that the elements of claim 1 in conjunction with an implant having differing cross-linking densities was allowable. As claim 40 does not include all the limitations of claim 1, it would not have been indicated as being allowable. As noted above, Krajicek discloses that the implant has portions with different degrees of tanning. Chvapil discloses that the degree of tanning is equivalent to the degree of cross-linking. Therefore, through inherency, the claimed limitations are met by Krajicek.

## Allowable Subject Matter

Claims 1-7,10,12-19,21-39 and 74-136 are allowed.

Claims 58-60 and 63 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

Art Unit: 3731

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Glenn K. Dawson whose telephone number is 571-272-4694. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Glehn K Dawson Primary Examiner Art Unit 3731 Page 6

Gkd 23 December 2005 Application/Control Number: 10/627,960 Page 7

Art Unit: 3731